

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NEOMYCINI SULFAS

EN

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Revision: 22/09/2023

Version: 01



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Neomycin sulfate Neomycini sulfas Neomycinesulfaat Néomycine (sulfate de) Neomycinsulfat
N° CAS:	1405-10-3
N° EC:	215-773-1

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin Sens. 1	H317
Resp. Sens. 1	H334
Repr. 2	H361
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

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H317	May cause an allergic skin reaction.
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H412	Harmful to aquatic life with long-lasting effects.
Precautionary statements:	
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/goggles/face shield.
P281	Use personal protective equipment as required.
P307+P311	IF exposed: Call a POISON CENTER or doctor/physician.
P314	Get medical advice/attention if you feel unwell.
P304+P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
Additional applicable label elements:	

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Neomycin sulfate
IUPAC name:	(2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-[(1R,2R,3S,4R,6S)-4,6-diamino-2-[[[2S,3R,4S,5R)-4-[(3R,4R,5S,6S)-3-amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy-3-hydroxy-5-(hydroxymethyl)oxolan-2-yl]oxy-3-hydroxycyclohexyl]oxyoxane-3,4-diol; sulfuric acid
Synonyms:	Neomycin B sulphate Neomycin trisulfate hydrate Framycetin sulfate Fradiomycin sulfate
N° CAS:	1405-10-3
N° EC:	215-773-1
Molecular Formula:	$C_{23}H_{46}N_6O_{13} \cdot x H_2SO_4$
Content:	Minimum of 680 IU/mg (dried substance). Mixture of sulfates of substances produced by the growth of certain selected strains of Streptomyces fradiae, the main component being the sulfate of 2-deoxy-4-O-(2,6-diamino-2,6-dideoxy- α -D-glucopyranosyl)-5-O-[3-O-(2,6-diamino-2,6-dideoxy- β -L-idopyranosyl)- β -D-ribofuranosyl]-D-streptamine (neomycin B).

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3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water fog. Neighbouring fires (containers exposed to fire): Water spray or water fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole

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Hazardous combustion products:

face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin and eyes. Do not swallow. Do not breathe dust. Eliminate all ignition sources. Contain release and eliminate its source. Evacuate area of unnecessary personnel.

For emergency responders

Avoid contact with skin and eyes. Do not swallow. Do not breathe dust. Eliminate all ignition sources. Contain release and eliminate its source. Evacuate area of unnecessary personnel.

6.2 Environmental precautions

Prevent release to the environment.

Prevent entry into sewers and watercourses.

If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Remove spilled material dry.

Avoid dust formation.

Place in a suitable container for disposal.

Provide ventilation and wash spill area.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Avoid contact with eyes. Keep away from sources of ignition.

Personal protection:

Wear suitable protective clothing in case of insufficient ventilation, use suitable respiratory equipment if you feel unwell.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in a dry, cool and well-ventilated place.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or yellowish-white powder, hygroscopic.

Odour: Odourless.

Odour threshold: Not available.

pH: 5.0 - 7.5 (50 g/L)

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

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Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Very slightly soluble in alcohol, practically insoluble in acetone.
Solubility in water:	Very soluble in water. 500 g/L
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular Weight: 615.00 g/mol

Density (25 °C): 0.448 g/mL

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

They do not occur.

10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures.

10.5 Incompatible materials

Oxidising agents.

10.6 Hazardous decomposition products

Decomposition by heat may produce toxic fumes of CO, CO₂, NO_x and SO_x.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 4325 mg/kg Dermal LD ₅₀ (rat): 200 mg/kg
Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	Causes eye irritation.

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Respiratory/skin sensitisation:	Irritating to mucous membranes and upper respiratory tract.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%.
Reproductive toxicity:	Possible risk of congenital malformations in the foetus.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: May cause allergic skin reactions. Aminoglycosides are associated with significant nephrotoxicity and ototoxicity.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	May cause an allergic skin reaction
Inhalation:	May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Degradation products are unlikely to occur in the short term. However, long-term degradation products may arise.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Avoid release into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not hazardous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not hazardous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not hazardous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not hazardous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not hazardous in transport.

14.6 Special precautions for user

Not hazardous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Harmful
Irritant.

Risk phrases:

R42 May cause sensitisation by inhalation.
R43 May cause sensitisation by skin contact.

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Safety phrases:

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

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For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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